QDRYL ALLERGY- diphenhydramine hydrochloride solution ATLANTIC BIOLOGICALS CORP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Q-dryl Allergy

Active ingredient (in each 5 mL = 1 tsp)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - sneezing
 - runny nose
 - itchy, watery eyes
 - itching of the nose or throat

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- use an accurate measuring device to administer this medication
- take every 4 to 6 hours

children under 2 years	do not use
children 2 to 5 years	ask a doctor
children 6 years to under 12 years	5 mL (1 tsp) to 10 mL (2 tsp); not more than 60 mL (12 tsp) in 24
	hours
adults and children 12 years and	10 mL (2 tsp) to 20 mL (4 tsp); not more than 120 mL (24 tsp) in 24
over	hours

Other information

- each tsp contains: sodium 5 mg
- store at 15°- 30°C (59°- 86°F)
- protect from freezing

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

Inactive ingredients

citric acid, D&C red #33, FD&C red #40, flavor, glycerin, poloxamer 407, polysorbate 20, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

Made in the **USA** for Qualitest Pharmaceuticals Huntsville, AL 35811

Distributed by

Atlantic Biologicals Corp

Miami Fl 33179

Rev. 3/15 R7 8273205 0823

PRINCIPAL DISPLAY PANEL

NDC 17856-1823-01

Q-dryl

Diphenhydramine Hydrochloride

Oral Solution

Antihistamine

Alcohol- Free - Cherry Flavor DELIVERS: 25 mg per 10 mL

UNIT DOSE 10 mL Cup

PACKAGING INFORMATION:

Dosage per Cup: 10 mL Cup(s) per Case: 72

See package insert for Drug Facts

Other Information:

Each (10 mL) contains: sodium 10 mg Store at 15° - 30° C (59° to 86°F) Protect from freezing

KEEP Q-DRYL AND ALL MEDICINES OUT OF THE REACH OF CHILDREN

Mfg for:

Qualitest Pharmaceuticals

Huntsville, AL 35811

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp. 20101 N.E. 16th Place Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments:

Call 1-800-509-7592

UDS Lot No: 111111 MFG Lot No: 0000000000 Exp. Date: 00/00/0000



QDRYL ALLERGY

diphenhydramine hydrochloride solution

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:17856-1823(NDC:0603-0823)

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE DIPHENHYDRAMINE 12.5 mg - UNII:8GTS82S83M) HYDROCHLORIDE in 5 mL

Inactive Ingredients

Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SUCROSE (UNII: C151H8 M554)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:17856-1823-	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	09/28/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/0 1/19 9 7	

Labeler - ATLANTIC BIOLOGICALS CORP (047437707)

Establishment				
Name	Address	ID/FEI	Business Operations	
ATLANTIC BIOLOGICALS CORP		047437707	repack(17856-1823), relabel(17856-1823)	

Revised: 10/2016 ATLANTIC BIOLOGICALS CORP